

**UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

|                                  |   |                              |
|----------------------------------|---|------------------------------|
| HEART IMAGING TECHNOLOGIES, LLC, | ) |                              |
|                                  | ) |                              |
| Plaintiff,                       | ) | <b>Case No. 1:12-cv-1020</b> |
|                                  | ) |                              |
| v.                               | ) |                              |
|                                  | ) |                              |
| MERGE HEALTHCARE INCORPORATED    | ) |                              |
|                                  | ) |                              |
| Defendant.                       | ) |                              |

**BRIEF IN SUPPORT OF MOTION FOR LEAVE TO CONDUCT LIMITED  
DEPOSITION OF DR. DAVID CLUNIE OR, IN THE ALTERATIVE, TO FILE  
SUPPLEMENTAL DECLARATION OF DR. SIMONETTI**

Plaintiff Heart Imaging Technologies, LLC, pursuant to Local Rules 26.1 and 104.4, has moved for leave to conduct a limited deposition of Dr. David Clunie, who is Defendant's Claim Construction expert and has submitted testimony on that issue. The basis for this motion is new publications by Dr. Clunie, made after the end of the claim construction discovery period, that contradict Dr. Clunie's declaration currently on file with the Court. In the alternative, Plaintiff requests leave to file the attached Supplemental Declaration of Dr. Simonetti, which discusses the Clunie documents that were not available at the time of Dr. Simonetti's previous Declaration.

**I. Statement of Facts**

1. On May 31, 2013, Dr. Clunie submitted a Declaration in support of Defendant's claim construction position in the Joint Claim Construction Statement (Doc.

No. 55, Ex. C). Dr. Clunie's Declaration included opinions that the term "to permit medical diagnosis" was insolubly ambiguous, (¶¶71-74) and that Plaintiff's definitions of "browser compatible" and "without requiring software executing outside the browser" were ambiguous because they used the phrase "without any plug-ins, applets, or similar software" (¶¶39, 57).

2. Pursuant to Local Patent Rule 104.4 and the Order on Joint Motion for Modified Case Schedule (Doc. No. 53), the parties had until June 21, 2013 to complete all claim construction discovery.

3. Plaintiff scheduled a deposition of Dr. Clunie for June 20, 2013.

4. On June 12, 2013, Plaintiff cancelled its deposition of Dr. Clunie, based on the information then available to it.

5. On July 24, 2013, Dr. Clunie published a blog post on David Clunie's Blog (Exhibit 1) describing the Invoke Image Display ("IID") Profile that he helped develop with the IHE (Integrating the Healthcare Enterprise) Radiology Technical Committee. The blog post included a discussion of diagnostic quality images and a set of slides (Exhibit 2) that indicate that one parameter that can be set on the IID Profile is "Diagnostic Quality," which can be set on or off at the selection of the user. Specifically, slide 8 shows a web browser request to view medical images with the option "diagnosticQuality=true", and slide 11 summarizes the "diagnosticQuality" option. Slide 13 states that the IID standard "requires servers to provide interactive viewing, and both review or diagnostic quality, and key images, under the control of the user."

6. On August 29, 2013, Dr. Clunie gave a presentation to the Clinical Operations Workgroup of the United States Office of the National Coordinator for Health Information Technology (ONC), a Federal Advisory Committee that makes recommendations on "a policy framework for the development and adoption of a nationwide health information infrastructure, including standards for the exchange of patient medical information." The presentation was recorded and transcribed (Exhibit 3) Dr. Clunie's slides (Exhibit 4) were published on the organization's website at <http://www.healthit.gov/FACAS/calendar/2013/08/29/standards-clinical-operations-workgroup>. Dr. Clunie's presentation cited the American Medical Association's Safety Panel's recommendation that "all medical image data distributed should be a complete set of images of diagnostic quality." (Exhibit 4, slide 3) In his transcribed statement, Dr. Clunie emphasized that the standard required that the images "had to be complete, they had to be diagnostic, and they had to be standard." (Exhibit 3, p. 3, last paragraph) In another part of his presentation, Dr. Clunie referred to the IHE Invoke Image Display standard, and noted that it "requires servers to provide at the request of the user: interactive viewing, review or diagnostic quality, or key images only." (Exhibit 4, slide 14) The presentation also stated that the term "zero footprint" "essentially means no help or (sic, helper) applications, no plug-ins, no applets, no Flash or Silverlight and maybe not even any JavaScript." (Exhibit 3, p. 7, first paragraph)

7. On September 7, 2013, Dr. Clunie published a blog post on David Clunie's Blog (Exhibit 5) expressing his opinion that "sharing" of images "requires the availability (download and transmission) of a complete set of images of diagnostic quality (CSIDQ)."

Dr. Clunie states that while lesser quality images, or less than a complete set of images, might be adequate for some situations, the choice should be the user's. He also stated that "it is essential that whatever technologies, architectures and standards are used to implement Download and Transmit (for Meaningful Use), that they be capable of supporting a CSIDQ." Dr. Clunie also stated that "The point of this post is that the safest general solution is to preserve whatever came off the modality. Doing anything less than that might be safe and sufficient, but you need to prove it." (Exhibit 5, top of p. 6) The blog post contained references to Dr. Clunie's testimony from August 29 (Exhibit 5, p. 6, paragraph beginning with "PPS") as well as the AMA standards discussed there that initiated the concept of CSIDQ (Exhibit 5, p. 7, paragraph beginning with "PPPS").

8. The IHE IID Trial Implementation referenced in Dr. Clunie's testimony was drafted by Dr. Clunie and contains a definition of the term Diagnostic Quality. It states that **"Diagnostic quality is display of a complete set of images with the quality required to make a diagnosis or clinical decision."** (Exhibit 6, lines 525-526) The Trial Implementation also states that "it is beyond the scope of this transaction to specify more detail, but regulatory authorities hold manufacturers to standards of performance according to a claim of diagnostic quality in the labeling of the device. The intent is that when the user requires and requests diagnostic quality, the quality should not be limited by the software, storage or transmission mechanisms used by the Image Display Actor." (Exhibit 6, lines 536-540)

9. None of the foregoing publications from Dr. Clunie were available to Plaintiff during the claim construction discovery period.

10. Plaintiff was notified by Defendant's counsel on October 7 that Dr. Clunie will be traveling out of the country until late November and would not be available to testify until early December. Plaintiff and Defendant have negotiated diligently to attempt to resolve this discovery dispute, but have been unable to reach a satisfactory resolution.

## **II. Questions Presented**

1. If a claim construction expert submits a declaration during the claim construction process, the expert subsequently publishes statements that contradict his testimony after the close of claim construction discovery, and the expert might not testify at the Claim Construction Hearing, should the opposing party be permitted to conduct a limited deposition of the expert to cross examine him on the statements prior to the Claim Construction Hearing?

2. If relevant publications relating to the interpretation of claim terms are published after the filing of claim construction expert testimony, should the parties' experts be permitted to file supplementary declarations addressing the new publications?

## **III. Argument**

Plaintiff elected not to depose Dr. Clunie during the claim construction discovery period (May 31 to June 21, 2013) based on the information available to it as of June 12, 2013. Since the close of that period, Dr. Clunie has published several new documents that conflict with his claim construction testimony. Plaintiff would like to introduce these documents at the Markman hearing. Because there is a possibility that Dr. Clunie will not appear at the Markman hearing, Plaintiff requests that it be allowed to take Dr.

Clunie's deposition prior to the Markman hearing to question him regarding these recent publications. In the alternative, Plaintiff requests leave to file a Supplemental Declaration of Dr. Simonetti addressing these recent publications.

Local Rule 26.1(d) requires parties requesting an extension of the discovery period or additional discovery to present the request before the expiration of the discovery period, to set forth good cause, and to show diligence. Local Rule 104.3(d) requires parties to identify the witnesses that they propose to call at the claim construction hearing and to provide a summary of their opinions. Local Rule 104.4 states that the parties shall complete all claim construction discovery, including depositions of experts, within thirty (30) days after filing the Joint Claim Construction Statement. Local Rule 104.5(c) provides that the Court may issue an order stating whether it will receive extrinsic evidence, and if so the particular evidence it will exclude and that it will receive, and any other matter the Court deems appropriate concerning the conduct of the Markman hearing.

Plaintiff is not requesting an extension of the overall discovery period or additional depositions, but is requesting that, if the Court elects to consider the extrinsic evidence offered by Dr. Clunie, that he be made available for a limited deposition on his publications made since the close of claim construction discovery on June 21, 2013. In the alternative, Plaintiff seeks leave file the attached Supplemental Declaration of Dr. Simonetti, which discusses the new Clunie publications that were not available when Dr. Simonetti's previous Declaration was filed.

**A. Plaintiff Has Diligently Pursued Discovery**

Plaintiff has diligently submitted interrogatories, document requests and deposition notices during the discovery period, which has not expired. During the claim construction phase of the discovery period, Plaintiff elected not to depose Dr. Clunie based on the information that was available to it at that time. The decision not to depose Dr. Clunie did not evidence lack of diligence – at the time, Plaintiff was not, and could not have been, aware of the contradictory publications made by Dr. Clunie after the close of the claim construction discovery period.

**B. There is Good Cause to Permit the Deposition**

**1. His Recent Publications Contradict Dr. Clunie's claim Construction Testimony**

**a. They indicate that diagnostic quality is not ambiguous**

Dr. Clunie's Declaration (Doc. No. 55, Ex. D) states:

"the meaning of each of the claim terms 'to permit medical diagnosis' and 'without loss of diagnostic data' is unclear and insolubly ambiguous to one of ordinary skill in the art.... The meaning of these terms is, at best, subjective."

(*Id.*, ¶71) In view of this, he rejected Plaintiff's proposed definitions of these terms, which were "without loss of diagnostically relevant information" and "without loss of information needed to permit a diagnosis."

However, in his recent publications, Dr. Clunie defines "diagnostic quality" as "display of a complete set of images with the quality required to make a diagnosis or clinical decision." (Exhibit 6, lines 525-526) The publication explains that "it is beyond the scope of this transaction to specify more detail, but regulatory authorities hold

manufacturers to standards of performance according to a claim of diagnostic quality in the labeling of the device. The intent is that when the user requires and requests diagnostic quality, the quality should not be limited by the software, storage or transmission mechanisms used by the Image Display Actor." (Exhibit 6, lines 536-540).

On August 29, 2013, Dr. Clunie gave a presentation to a Federal Advisory Committee that makes recommendations on health information infrastructure, including standards for the exchange of patient medical information. (Exhibits 3 and 4) Dr. Clunie's presentation cited the American Medical Association's Safety Panel's recommendation that "all medical image data distributed should be a complete set of images of diagnostic quality." (Exhibit 4, slide 3) In his transcribed statement, Dr. Clunie emphasized that the standard required that the images "had to be complete, they had to be diagnostic, and they had to be standard." In another part of his presentation, Dr. Clunie referred to the IHE Invoke Image Display (IID) standard, and noted that it "requires servers to provide at the request of the user: interactive viewing, review or diagnostic quality, or key images only." (Exhibit 4, slide 14).

On September 7, 2013, Dr. Clunie posted a blog expressing his opinion that "sharing" of images "requires the availability (download and transmission) of a complete set of images of diagnostic quality (CSIDQ)." He explained that, in the context of "sharing" images, "it is essential that whatever technologies, architectures and standards are used to implement Download and Transmit (for Meaningful Use), that they be capable of supporting a CSIDQ." (Exhibit 5).



In a set of slides published on Dr. Clunie's blog in July (Exhibit 2), he states that the IHE Invoke Image Display standard "requires servers to provide interactive viewing, and both review or diagnostic quality, and key images, under the control of the user."

Dr. Clunie's testimony that "to permit diagnosis" and "without loss of diagnostic data" are insolubly ambiguous is contradicted by his own repeated use of these terms to define diagnostic quality in his publications. In particular, Dr. Clunie's definition of diagnostic quality as "the quality required to make a diagnosis" contradicts his testimony that the term "to permit medical diagnosis" is insolubly ambiguous.

**b. They indicate that Plaintiff's definition of browser compatible/software running outside a browser is not ambiguous**

Dr. Clunie testified that Plaintiff's definitions for "browser compatible" and "without requiring software executing outside an Internet web browser" were ambiguous because they used the phrase "without any plug-ins, applets, or similar software" (Doc. No. 55, Ex. C, ¶¶ 39, 57). He stated that "the inclusion of the limitation "without any plug-ins, applets, or similar software" in any construction only serves to introduce a new and unnecessary layer of ambiguity and confusion to a term that should be afforded its plain and ordinary meaning." *Id.*

However, in one of his recent publications, Dr. Clunie stated that the term "zero footprint" "essentially means no help or (sic, helper) applications, no plug-ins, no applets, no Flash or Silverlight" (Exhibit 3, p. 7, first paragraph). This definition of "zero footprint" is virtually identical to the definitions proposed by Plaintiff for these terms. Dr. Clunie's description of "zero footprint" viewers as not requiring "helper applications,

plug-ins, applets, Flash, and Silverlight" in his Blog post indicates that these terms have a definite meaning and are not ambiguous.

Dr. Clunie's recent publications are consistent with the Plaintiff's construction of "browser compatible format" and "without requiring software executing outside the Internet web browser," and contradict his disparagement of Plaintiff's constructions.

**2. The Publications Are Relevant to Claim Construction and Should be Considered at the Markman Hearing**

**a. They relate to Dr. Clunie's credibility**

Dr. Clunie's Declaration supporting claim construction is in the record and could be considered by the Court. The contradictory statements in Dr. Clunie's recent publications are, at a minimum, relevant to Dr. Clunie's credibility. The Court will want to know how Dr. Clunie can reconcile his sworn testimony with his contradictory publications, and the best way to address this question is to permit his deposition, where Plaintiff can cross examine him on the documents.

**b. They are also intrinsically relevant to the claim construction**

Dr. Clunie is offered to the Court as an expert in the field of medical imaging, and his publications are substantive evidence that is relevant to the issue of claim construction. If a deposition is not permitted, Plaintiff requests that the Court permit it to submit the attached Supplemental Declaration of Dr. Simonetti, which will introduce and discuss these exhibits.

**3. Dr. Clunie May Not Attend the Markman Hearing**

If Dr. Clunie testifies at the Markman hearing, Plaintiff would be able to cross examine him on these recent publications. However, Dr. Clunie may not be available when the hearing is scheduled, or Merge may decide not to bring him to the hearing. Heart IT therefore requests permission to depose Dr. Clunie, or in the alternative, to have Dr. Simonetti introduce the documents.

**4. Merge would not be prejudiced by a limited deposition on the recent publications**

Merge would not be prejudiced by a limited deposition of Dr. Clunie. In correspondence between counsel, Merge has already offered to permit Plaintiff to conduct a limited deposition of Dr. Clunie on another topic. There would thus be no significant additional cost or effort required by Merge or Dr. Clunie if the Court ordered a limited deposition focusing on the apparent contradictions between his Declarations and his recent publications.

**5. Merge would not be prejudiced by the Supplemental Declaration of Dr. Simonetti**

Plaintiff's alternative remedy is filing the attached Supplemental Declaration of Dr. Simonetti. The Supplemental Declaration is narrowly tailored to introduce and discuss the newly published documents of Dr. Clunie. Plaintiff would not object to permitting Dr. Clunie to similarly supplement his Declaration to address the new documents. The supplementation of the Declaration to add material that were not available to the parties earlier in the claim construction process will impose no significant

burden on the parties, and will permit the Court to have a more complete understanding of the claim terms and their understanding by those of skill in the art.

#### **IV. Conclusion**

Plaintiff respectfully requests that the Court permit a deposition of Dr. David Clunie limited to his recent publications and their relationship to his claim construction testimony. In the alternative, Plaintiff requests leave to file the attached Supplemental Declaration of Dr. Simonetti.

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on October 28, 2013, the foregoing document was electronically filed with the Clerk of Court using the CM/ECF system which will send notification of such filing to all counsel of record.

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